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10/520,497	09/14/2005	Huazhong Shi	023070-127310US	9783

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EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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09/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,497	Applicant(s) SHI ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's Request for Continued Examination and amendment filed July 28, 2008.. Claims 30-40 are pending and are examined. All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

2. Claims 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 30 and 36, it is suggested that "identical" be amended to "sequence identity" to indicate structural identity and not functional identity or other identities.

Claims 30 and 36 recites "90% identical to SEQ ID NO:10 and is less than 530 amino acids in length". However, SEQ ID NO:10 has only 454 amino acids. It is unclear what other amino acids are encompassed by these claims.

These claims have 3 recitations of "comprising" and "comprises", as well as "encoding", which are open language. However, the claims also recite "a truncated NHX1 polypeptide", "a C-terminal deletion" and "less than 530 amino acids". Thus, the metes and bounds of these claims are unclear.

Clarification and/or correction are required.

Applicant indicates the claims encompass "polypeptides of between about 454 amino acids and about 530 amino acids".

Applicant's traversal is unpersuasive because "about" implies a range, and thus "about 530 amino acids" would encompass a value greater than 530 amino acids. If "less than 530 amino acids" could be more than 530 amino acids, then the claims remain unclear.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 30-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 30 and 36, Applicant is invited to point to the page and line number in the originally filed specification where "90% identical to SEQ ID NO:10 and is less than 530 amino acids" can be found. While "90% identical to SEQ ID NO:10" has support, it is not supported in combination with "less than 530 amino acids".

Similarly, in claims 33, 34, 39 and 40, "less than 500 amino acids" and "less than 475 amino acids" were not disclosed in conjunction with "90% identical to SEQ ID NO:10".

Further, Applicant is invited to point to the page and line number in the originally filed specification where "compared to a plant that lacks the NHX1 polynucleotide sequence" can be found. While "compared to a plant where the polynucleotide was not introduced" has support in originally filed claim 1, this is not synonymous with the current recitation. Since the NHX1 sequence is naturally present in certain non-

transgenic plants, these non-transgenic plants would not be lacking the NHX1 sequence, even though the NHX1 sequence was not introduced.

Absent of such support, Applicant is required to cancel the new matter in response to this Office action.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 30, 33-36, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:9 and 10, does not reasonably provide enablement for 90% sequence identity to SEQ ID NO:10 and confers Na⁺ tolerance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for reasons of record.

Applicant traverses primarily that three C-terminal deletion mutants show higher Na⁺ tolerance than the full length form; the specification provides guidance as to how to test for Na⁺ tolerance; and Figure 6 provides sufficient guidance with regard to functional domains in the AtNHX1 protein.

Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. Applicant's arguments are not commensurate in scope with the claims. 90% sequence identity encompasses unspecified substitutions, insertions, deletions, and combinations thereof while retaining "increased Na⁺ tolerance" function. The specification does not disclose any working examples of 90% sequence identity to SEQ ID NO:10 or any C-terminal deletions to SEQ ID NO:10.

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In Table 1, of the 23 site mutations, 20 mutations failed to show increased Na⁺ tolerance. Further, 2 of 3 N-terminus deletions showed *decreased* Na⁺ tolerance compared to wildtype. These results indicate it is highly unpredictable what sequences within the 90% sequence identity population would increase Na⁺ tolerance. The limitations of "C terminal deletion" and "less than 530 amino acids" do not address this issue because SEQ ID NO:10 has only 454 amino acids, and thus the C-terminal deletion most likely refers to the wildtype sequence (SEQ ID NO:2) and does not affect SEQ ID NO:10 at all. With regard to guidance for testing for Na⁺ tolerance, before plants containing different mutations can be tested for Na⁺ tolerance, one skilled in the art must be able to make these mutant sequences having increased Na⁺ tolerance without undue experimentation. Since it is highly unpredictable as to which mutations would increase Na⁺ tolerance for the reasons indicated above and of record, the amount of experimentation required to practice the invention as commensurate in scope with the claims is deemed to be excessive and undue. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 112, first paragraph

4. Claims 30, 33-36, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record.

Applicant traverses, stating that Applicant is not required to reduce to practice every species encompassed by the claims; the specification provides detailed sequence information about the AtNHX1 protein and a large number of mutants; Figure 6 gives the location of transmembrane domains, Na⁺ and H⁺ binding domains, N-terminal and C-terminal regions, the 23 mutations, and the 6 truncated forms from Table 1; and the specification sets forth assays for preparing and identifying such variants.

Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. Applicant has not reduced to practice a single species encompassed by the claims. That is, Applicant does not teach a C-terminal deletion to a sequence having 90% sequence identity to SEQ ID NO:10. With regard to the mutants, of the 23 mutant constructs made, 20 failed to show increased Na⁺ tolerance (Table 1). Therefore, Applicant has not described a representative number of species within the claimed genus which has increased Na⁺ tolerance, and one skilled in the art cannot reliably predict the structures of mutants which have the "increased Na⁺ tolerance" function based upon Applicant's disclosure. Figure 6 is not persuasive because no meaningful correlation can be made between the structures claimed (what mutations) and function associated with those structures. Only 1 of 9 in the proposed Na⁺ binding region and none of the mutants in the proposed amiloride, H⁺ and pH binding regions showed increased Na⁺ tolerance. The other 2 of 23 mutations which showed increased Na⁺ tolerance are in the C-terminal region which corresponds to the C-terminal deletions. Note that these mutations were made to wildtype SEQ ID NO:2 (538 amino acids) and not to SEQ ID NO:10 (454 amino acids). Since the mutants

having increased Na⁺ tolerance are not adequately described, assays for preparing and identifying these mutants are also not adequately described. Accordingly, for these reasons and reasons of record, the claimed invention lacks adequate written description.

Claim Rejections - 35 USC § 102

5 Claims 30-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaxiola et al. (PNAS, Vol. 96, No. 4, pp. 1480-1485, Feb 1999). The open language in these claims reads on a sequence containing SEQ ID NO:10. Gaxiola teaches a vector and sequence having 100% sequence identity to SEQ ID NO:10. Accordingly, Gaxiola anticipated the claimed invention.

Applicant traverses that the claims are directed to C-terminal truncated NHX1 polypeptides that are less than 530 amino acids in length.

As indicated in the 112, 2nd paragraph rejection above, these claims have 3 recitations of “comprising” and “comprises”, as well as “encoding”, which are open language. SEQ ID NO:10 is 454 amino acids, which is less than 530 amino acids. The C-terminal deletion was taken from SEQ ID NO:2 and not SEQ ID NO:10. While the sequence of the prior art is 538 amino acids, it contains SEQ ID NO:10. Accordingly, this rejection is maintained.

Remarks

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phuong T. Bui/

Primary Examiner, Art Unit 1638

4/29/08